

42



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10/083,727	02/27/2002	Radislav Alexandrovich Potyrailo	RD-28,645	6196

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General Electric Company  
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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 05/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/083,727

Applicant(s)

POTYRAILO ET AL

Examiner

BJ Forman

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) 18-31, 41-54 and 59-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 32-40 55-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

Art Unit: 1634

## **FINAL ACTION**

### ***Status of the Claims***

1. This action is in response to papers filed 22 February 2004 in which the rejections in the Office Action of 21 November 2003 were traversed.

Applicant's arguments have been thoroughly reviewed and are discussed below.

The previous rejections under 35 U.S.C. 112, second paragraph and under 35 U.S.C. 102(a), 102(e) and 103(a) are maintained.

Claims 1-17, 32-40, 55-58 are under prosecution.

### ***Claim Objections***

2. Claim 14 objected to because of the following informalities: The comma between "dipping draining" is missing.

Appropriate correction is **required**.

### ***Response to Arguments***

3. Applicant acknowledges the above object and requests the objection be withdrawn because, as an informality, it will be corrected following allowance. Applicant's request has been considered. However, as noted above, correction is required.

While Applicant may consider the missing comma a mere informality, the presence or absence of a comma influences the meaning of the claim i.e. the meaning of "dripping draining" differs from that of "dripping, draining". In an effort to facilitate prosecution and prevent the need for 312 amendments after allowance, the examiner has interpreted the

Art Unit: 1634

missing comma as a typographical error, informed Applicant of the error and required the claim be amended to correct the error.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-17, 32-40, 55-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1-17, 32-40, 55-58 are indefinite in Claim 1 because the claim is drawn to a method of generation and screening three dimensional array, but the claim does not recited method steps of screening. Therefore, it is unclear whether the method steps perform the claimed method.

b. Claims 1-17, 32-40, 55-58 are indefinite in Claim 1 for the recitation “(x, y, and z)” because it is unclear whether a recitation within parenthesis adds limitations to the claims.

c. Claims 1-17, 32-40, 55-58 are indefinite in Claim 1, lines 7 & 8 for the recitation “the sample array” because the recitation lacks proper antecedent basis in the “array of samples” recited in line 6. It is suggested that Claim 1 be amended to provide proper antecedent basis.

d. Claim 2 is indefinite for the recitation “the array comprises multiple two dimensional arrays” because it is unclear what limitations are being added to the method steps of Claim 1. The recitation is further indefinite because Claim 1, line 6 recites “to generate a three dimensional array”. As such it is unclear whether the limitations of Claim 2 the three-dimensional array of Claim 1 or to additional arrays not described in Claim 1.

Art Unit: 1634

e. Claims 3 and 5-17 are indefinite in Claim 3 for the recitation “comprises samples deposited on the surface” because it is unclear whether the recitation describes the array or whether the recitation is intended to be a method step of depositing on the surface.

f. Claims 3 and 5-17 are indefinite in Claim 3 further indefinite for the recitation “the surface” because the recitation lacks proper antecedent basis in Claim 1.

g. Claim 4 is indefinite for the recitation “the use of masking and gradient deposition” because it is unclear whether the recitation is intended as a method step of masking and gradient deposition. It is suggested that the claim be amended to recite positive and active method steps e.g. “wherein said depositing comprises masking and gradient deposition”.

h. Claims 5-7 are indefinite in Claim 5 for the recitation “further comprising evaporative methods for depositing” because it is unclear whether the recitation is an additional (i.e. further) method step or whether the recitation is intended to define the depositing step of Claim 1.

i. Claim 7 is indefinite for the recitation “further comprising molecular beam epitaxy” because it is unclear whether the recitation is an additional (i.e. further) method step or whether the recitation is intended to define the evaporative method of Claim 5.

j. Claims 8 and 9 are indefinite in Claim 8 for the recitation “further comprising glow-discharge processes for deposition” because it is unclear whether the recitation is an additional (i.e. further) method step or whether the recitation is intended to define the depositing step of Claim 1.

k. Claim 9 is indefinite for the recitation “further comprising chemical vapor deposition” because it is unclear whether the recitation is an additional (i.e. further) method step or whether the recitation is intended to define the depositing step of Claim 1.

l. Claim 12 is indefinite for the recitation “further comprising pulsed-laser deposition for deposition” because it is unclear whether the recitation is an additional (i.e. further) method step or whether the recitation is intended to define the depositing step of Claim 1.

Art Unit: 1634

m. Claims 13 and 14 are indefinite in Claim 13 for the recitation “further comprising mechanical deposition” because it is unclear whether the recitation is an additional (i.e. further) method step or whether the recitation is intended to define the deposition of Claim 1.

#### **Response to Arguments**

6. Applicant traverses the above rejections and argues that the employed language falls within the bounds of current claim language. Applicant’s argument has been considered but is not found persuasive. Applicant merely states that the claims recite current claim language but has not addressed any one of the above rejections. The above rejections address numerous and differing issues concerning claim language. Applicant has not addressed these issues thereby providing an argument persuasive for withdrawing the rejection. Because Applicant has not addressed any of the specific issues above or amended to claims to overcome the above rejections, the claims are still deemed indefinite. The rejections are maintained and made final.

#### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

Art Unit: 1634

subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-3, 5-6, 13-17, 32-37, 39-40, 55-58 are rejected under 35 U.S.C. 102 (a) and (e) as being anticipated by Walt et al (U.S. Patent No. 6,327,410, issued 4 December 2001).

Regarding Claim 1, Walt et al disclose a method for generation and screening of three dimensional arrays comprising, depositing a plurality of samples onto at least one substrate at discrete and defined positions in a three dimensional format such that each sample is isolated from other samples (i.e. attached to a microsphere), collecting data from the sample array, correlating data to the position of the sample and analyzing the data (Column 3, lines 30-45 and Column 22, lines 8-26) and wherein each sample is defined by x, y, z coordinates i.e. x and y being the axis of the substrate (Column 6, lines 4-21) and z being the size/diameter of the microsphere (Column 19, lines 6-12) and/or presence or absence of bead (Column 18, lines 35-40).

Regarding Claim 2, Walt et al disclose the method wherein the array comprises multiple two-dimensional arrays i.e. sub-arrays within the array (Column 18, line 59-Column 19, line 5).

Regarding Claim 3, Walt et al disclose the method wherein the array comprises samples on the surface of a three-dimensional structure i.e. microsphere (Column 11, lines 41-67).

Regarding Claim 5, Walt et al disclose the method wherein evaporative methods for deposition is used i.e. the microsphere solution is evaporated (Column 17, lines 46-59).

Regarding Claim 6, Walt et al disclose the method wherein the evaporative methods utilized filaments i.e. optical fibers (Column 17, lines 11-59).

Regarding Claim 13, Walt et al disclose the method comprising mechanical deposition (Column 17, lines 46-59).

Art Unit: 1634

Regarding Claim 14, Walt et al disclose the method mechanical deposition comprises flow coating i.e. dripping (Column 17, lines 46-59).

Regarding Claims 15-17, Walt et al disclose the method wherein the samples have a thickness ranging from 10nm to 200µm i.e. microsphere diameter range (Column 7, lines 32-40).

Regarding Claim 32, Walt et al disclose the method further comprising treating the deposited samples to initiate a chemical reaction within the array i.e. contacting the array with bioagent-specific analytes (Column 19, line 54-Column 21, line 60).

Regarding Claim 33, Walt et al disclose the method wherein the treatment comprises addition of a chemical agent e.g.  $\text{Ca}^{2+}$ ,  $\text{Mg}^{2+}$  (Column 20, Table III).

Regarding Claim 34, Walt et al disclose the method wherein treatment is applied differentially to at least some of the locations of the array i.e. selected sites are photoactivated for microsphere attachment (Column 18, lines 41-47).

Regarding Claim 35, Walt et al disclose the method wherein the treatment is applied in a constant manner to all locations of the array (Example 1, Column 26, lines 50-65).

Regarding Claim 36, Walt et al disclose the method wherein treatment comprises application of electromagnetic radiation i.e. light (Column 15, line 64-Column 16, line 20). Walt et al teach the method wherein following addition of bioagent-specific analytes the microspheres are treated (exposed to) light. The open claim language “comprises” encompasses the treatment steps of Walt et al.

Furthermore, Walt et al disclose the method wherein light is applied to the microspheres to chemically link the microspheres to the fiber optic substrate (Column 18, lines 41-47).

Regarding Claim 37, Walt et al disclose the method wherein the treatment comprises the application of ultrasound i.e. sonication (Column 17, lines 31-52 and Column 18, lines 33-35).



Art Unit: 1634

Regarding Claim 39, Walt et al disclose the method wherein the substrate is substantially inert i.e. optical fiber substrate comprising microspheres (Column 5, lines 49-60).

Regarding Claim 40, Walt et al disclose the method wherein the substrate comprises a substance that interacts with at least some of the samples of the array i.e. the optical fibers comprises photoactivatable linkers for chemical attachment of the microspheres (Column 18, lines 41-47) and the microspheres comprise functional groups for sample (bioactive agent) interaction (Column 11, line 63-Column 12, line 25). Therefore both, the optical fiber substrate and microsphere substrate meet the limitations of the claim.

Regarding Claim 55, Walt et al disclose the method wherein collecting analytical data from the array is substantially simultaneous for each sample of the array (Example 1, Column 26, lines 36-60).

Regarding Claim 56, Walt et al disclose the method wherein collecting analytical data from the array is performed separately for each sample i.e. individual microspheres (Column 16, lines 59-63).

Regarding Claim 57, Walt et al disclose the method wherein the analysis comprises univariate analysis (Column 16, lines 59-63).

Regarding Claim 58, Walt et al disclose the method wherein the analysis comprises multivariate analysis (Example 1, Column 26, lines 25-60).

### **Response to Arguments**

9. Applicant argues that the instant claims are drawn to a plurality of sample defined by its (x, y, and z) coordinate. Applicant points to paragraph 45 of the instant specification to define the claimed coordinate. Applicant's arguments have been considered but are not found persuasive. First, while the claims are read in view of the specification, limitations from the specification (i.e. mathematical terminology) are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Second, as stated above in ¶ 5b, the claims are indefinite for reciting "x, y and z" within parenthesis (x, y and z) because it is

Art Unit: 1634

unclear how or whether a recitation within parenthesis limits the claim. Finally, as stated directly above, Walt et al teach their method wherein the microspheres and samples thereon are defined by x, y, and z coordinates wherein the x and y coordinates define the position on the planar substrate and the z coordinate defines the size/diameter and/or presence/absence of the microsphere (Column 6, lines 4-21 and Column 18, lines 35-40). As such, Walt et al describe the coordinates as recited in Claim 1.

Applicant further argues that the instant invention differs from Walt et al in that each sample is defined by its position in space. The argument has been considered but is not found persuasive because the claims are drawn to a sample defined by "its (x, y and z) coordinate". While the claims are read in view of the specification, limitations from the specification (i.e. defined by its position in space) are not read into the claims. The teaching of Walt et al is discussed above. In view of the indefinite claim language, Walt et al anticipates the instantly claimed invention.

### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1634

11. Claims 4, 7-12 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al (U.S. Patent No. 6,327,410, issued 4 December 2001) in view of Chen et al (U.S. Patent No. 6,638,760, filed 3 December 1998).

Regarding Claims 4 and 7-12, Walt et al teach the method for generation and screening of three dimensional arrays comprising, depositing a plurality of samples onto at least one substrate at discrete and defined positions in a three dimensional format such that each sample is isolated from other samples (i.e. attached to a microsphere), collecting data from the sample array, correlating data to the position of the sample and analyzing the data (Column 3, lines 30-45 and Column 22, lines 8-26) and wherein each sample is defined by x, y, z coordinates i.e. x and y being the axis of the substrate (Column 6, lines 4-21) and z being the size/diameter of the microsphere (Column 19, lines 6-12).

Walt et al further teach that the method further comprises masking (Column 18, lines 41-47) and any of a variety of deposition techniques known in the art (Column 11, line 63-Column 12, line 64) which suggests that any deposition technique would function equally well in their method. But they do not specifically teach gradient deposition, molecular beam epitaxy, glow-discharge deposition, chemical vapor deposition or pulsed-laser assisted deposition.

However, Chen et al teach a similar method for generation and screening of three dimensional arrays and they also teach that variety of deposition techniques known in the art are useful for creating the desired arrays having appropriate density e.g. chemical vapor deposition (Column 10, lines 21-47).

Therefore, because Walt et al and Chen et al teach that any deposition techniques known in the art would function equally and because the claimed deposition techniques were known in the art, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply gradient deposition, glow-discharge deposition, chemical

Art Unit: 1634

vapor deposition or pulsed-laser assisted deposition to the deposition of Walt et al based on available equipment and desired results.

Regarding Claim 38, Walt et al teach the method further comprising treating deposited samples to initiate a chemical reaction e.g. hybridization (Column 19, line 54-Column 21, line 60, especially Column 21, lines 17-60) but they are silent regarding the treatment comprising a change in temperature. However, Chen et al teach the similar method comprising treating samples to initiate hybridization comprising changing the temperature i.e. heating to 37° C to hybridize and further heating to 98° C to denature (Column 22, lines 13-62). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the temperature change of Chen et al to the hybridization of Walt et al for the obvious benefits of sequencing specifically captured molecules as taught by Chen et al (Column 22, lines 13-62).

#### **Response to Arguments**

12. Applicant relies on the arguments discussed above regarding Walt et al to overcome the obviousness rejections above. Applicant's arguments have been considered but are not found persuasive as discussed above.

#### **Prior Art**

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

a. Labaer et al (U.S. Patent Application Publication No. 2002/0192673, filed 22 January 2002 with priority to 23 January 2001) teach three-dimensional substrates (¶ 330-334).

Art Unit: 1634

b. Campbell et al (U.S. Patent No. 6,168,914, issued 2 January 2001) teach three-dimensional substrate (Fig. 1-5).

c. Patek et al (U.S. Patent No. 6,541,211, filed 24 November 1999) teach three-dimensional substrates (Fig. 5 and Column 10, lines 51-67).

d. Baum (U.S. Patent Application Publication No. 2003/0068644, filed 20 May 1998) teaches three-dimensional substrates (Fig. 13, 25-29).


#### **Conclusion**

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
BJ Forman, Ph.D.  
Primary Examiner  
Art Unit: 1634  
May 4, 2004